

MENTORED SCIENTIST DEVELOPMENT AWARD IN RESEARCH ETHICS

Release Date: January 22, 1999

PA NUMBER: PA-99-050

P.T.

National Institutes of Health
Centers for Disease Control
Health Resources and Services Administration
Agency for Health Care Policy and Research
Substance Abuse and Mental Health Services Administration

Application receipt date: March 6

PURPOSE

The National Institutes of Health, Centers for Disease Control, Health Resources and Services Administration, Substance Abuse and Mental Health Services Administration, and the Agency for Health Care Policy and Research invite biomedical, behavioral, and public health researchers to apply for the Mentored Scientist Development Award (MSDA). The MSDA will support training in research ethics for health professionals working at academic and other health-related institutions in biomedical, behavioral, or public health research, particularly research involving human participants.

The goals of the MSDA are two fold. First, the award should enhance the career of the candidate such that he or she would become an independent investigator in applied research ethics, and second, the candidate would become a resource in the area of research ethics for the sponsoring institution and its scientific community. As such, applications for the MSDA should include a mentored research experience that will measurably enhance the candidate's scientific career as a research ethicist.

This MSDA program is intended to support two kinds of individuals: (1) Those who have an established career in another field (such as clinical medicine, nursing, biomedical or behavioral research, or have a background in the humanities), and now want to move into research ethics; and (2) Those who are already in the field of research ethics but, because of their junior status,

require a period of mentored career development in order to become independent scientists in the field of research ethics.

Although this Program Announcement applies to several agencies, it will be administered according to NIH policies. This initiative together with a parallel Program Announcement, Short-Term Courses in Research Ethics (T15), are steps towards developing a comprehensive program in research ethics. As used in this program announcement, research ethics refers to ethical, legal, and social principles guiding the responsible conduct of research, particularly focusing on scientific integrity and protection of the interests of research participants.

This initiative follows a directive from the Secretary of Health and Human Services in response to President Clinton's apology to the survivors and relatives of the men who participated in the Tuskegee Syphilis Study. The directive requires DHHS agencies to offer training - with special outreach to minority scientists - for post-graduate training in research ethics and for the development of short courses in research ethics.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Mentored Scientist Development Award in Research Ethics, is related to the priority area of human resource development. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) from the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-512-1800).

ELIGIBILITY

The candidate must have a research or a health-professional doctorate or its equivalent and should have demonstrated the capacity or have shown the potential for highly productive, independent postdoctoral research in her or his chosen field prior to applying for this award. Individuals with doctorates in the humanities are also eligible to apply.

The candidate must identify a mentor with extensive research and academic experience in ethical issues related to biomedical research and must be willing to commit a minimum of 75 percent of his or her full-time professional effort to conducting research and pursuing research career

development activities for the period of the award. It is important that the mentor be an individual with established credentials in the field of research ethics.

Applications should be submitted by the candidate directly and should include a letter of commitment from the proposed institution. Applicants may be members of domestic, non-federal, public or private organizations, such as medical, dental, public health, or nursing schools or other institutions of higher education. Minorities, women, and individuals with disabilities are encouraged to apply. Candidates must be U.S. citizens or noncitizen nationals or must have been lawfully admitted for permanent residence. Individuals on temporary or student visas are not eligible. Current principal investigators of research grants from NIH or any of the other sponsoring agencies are not eligible.

MECHANISM OF SUPPORT

Awards from this PA will use the K01 mechanism, which provides an additional period of support to a doctoral-level candidate in a new research area or in an area that would enhance the candidate's career in research ethics. The candidate and mentor are responsible for the planning, direction, and execution of the program on behalf of the applicant institution. Candidates must show the capacity or potential for highly productive, independent careers in the field of research ethics.

The project period is for three, four, or five years depending upon prior experience and the need for additional research experience. Awards are not renewable.

RESEARCH OBJECTIVES

Recent advances in biomedical and behavioral research and their application to human research have highlighted the importance of ethical issues in these areas. The advent of genetic therapies, xenotransplantation, HIV vaccine trials, the testing of therapies which preclude informed consent (e.g., coma and severe trauma), as well as recent attention to past abuses such as the Tuskegee Syphilis Study have catalyzed a realization that greater emphasis on research ethics is needed.

As part of the plan to address this issue, the sponsoring agencies have chosen to increase the cadre of researchers trained in the social, legal, and ethical issues arising from biomedical, behavioral, and public health research. The areas described below, although not exhaustive, represent critical scientific areas where research can substantially inform public policy in this field. Researchers proposing training in other areas must show the relevance of such training to social,

legal, and ethical issues in biomedical, behavioral, nursing, social science, or public health research.

- o Ethical and legal guidance for protection of human participants in research.
- o Scientific integrity and responsibility.
- o Interplay of medical and research ethics in clinical research.
- o Privacy and confidentiality protections for research participants.
- o Implications of innovations in biotechnology and biomedical research; new risks to participants from developing laboratory and information technology.
- o Ethics review processes in research organizations and institutions - value and benefits.
- o Cultural issues in ethical principles and standards.
- o Ethical issues related to health services research.

Environment

The institution must have a well-established academic program in research ethics or a related field. It must have suitable library facilities and make a commitment to assist the trainee with access to institutional resources (such as a hospital or research environment) suitable for the proposed field of study. It must provide qualified faculty to serve as mentors. The institution must be able to demonstrate a commitment to the development of the candidate as a productive, independent investigator. The candidate, mentor, and institution must be able to describe a career development program that will maximize the use of relevant research and educational resources.

Program

The award provides three to five years of funding. At least 75 percent of the recipient's full-time professional effort must be devoted to the program, and the remainder devoted to other research-related and/or teaching pursuits consistent with the objectives of the award. For example, if the applicant has proposed a research plan involving ethical issues in clinical research, continuation of his or her current activities in that area could be considered "other research-related pursuits." The candidate may find it appropriate to include relevant didactic and laboratory or field research experiences.

Mentor

The recipient must receive appropriate mentoring throughout the three- to five-year program. The mentor should be a senior individual who is well known in the field of research ethics. Because suitable mentors may not be available at the applicant institution, applicants may choose a reasonable and workable mentorship from another institution.

Allowable Costs

1. Salary: This award will provide salary and fringe benefits for the recipient up to \$50,000 per year (plus fringe benefits). In addition, the institution may supplement this contribution up to a level that is consistent with the institution's salary scale; however, supplementation may not be from Federal funds unless specifically authorized by the program from which such funds are derived. Institutional supplementation of salary must not require extra duties or responsibilities that would interfere with the purpose of the MSDA. Continuation of clinical or research activities that relate to the proposed area of concentration in research ethics is acceptable.

The total salary requested must be based on a full-time, 12-month staff appointment. It must be consistent both with the established salary structure at the institution and with salaries actually provided by the institution from its own funds to other staff members of equivalent qualifications, rank, and responsibilities in the department concerned. If full-time, 12-month salaries are not currently paid to comparable staff members, the salary proposed must be appropriately related to the existing salary structure.

2. Research Development Support: This award will provide up to \$20,000 per year for the following expenses: (a) tuition, fees, and books related to career development; (b) research expenses, such as supplies, equipment, and technical personnel; (c) travel to research meetings or training, including at least one meeting convened by the NIH for awardees to discuss research progress; (d) statistical services, including personnel and computer time.

3. Ancillary Personnel Support: Salary for mentors or secretarial or administrative assistance is not allowed.

4. Facilities and Administrative Costs: These costs will be reimbursed at eight percent of modified total direct costs or at the actual cost rate, whichever is less.

Evaluation

In carrying out its stewardship of human resource-related programs, the HHS may request information essential to an assessment of the effectiveness of this program. Accordingly, recipients are hereby notified that they may be contacted after the completion of this award for periodic updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program.

Other Income

Fees resulting from clinical practice, professional consultation, or other comparable activities required by research and the career award recipient may not retain research-related activities of this award. Such fees must be assigned to the grantee institution for disposition by any of the following methods:

The funds may be expended by the grantee institution in accordance with the HHS/NIH policy on supplementation of career award salaries and to provide fringe benefits in proportion to such supplementation. Such salary supplementation and fringe benefit payments must be within the established policies of the grantee institution.

The funds may be used for health-related research purposes.

The funds may be paid to miscellaneous receipts of the U.S. Treasury. Checks must be made payable to the Department of Health and Human Services, NIH, and forwarded to the Director, Division of Financial Management, NIH, Bethesda, Maryland 20892. Checks must identify the relevant award account and reason for the payment.

Awardees may retain royalties and fees for activities such as scholarly writing, service on advisory groups, or honoraria from other institutions for lectures or seminars, provided these activities remain incidental and provided that the retention of such pay is consistent with the policies and practices of the grantee institution.

Usually, funds budgeted in an HHS/NIH-supported research or research training grant for the salaries or fringe benefits of individuals, but freed as a result of a career award, may not be re-budgeted. The awarding component will give consideration to approval for the use of released funds only under unusual circumstances. Any proposed retention of funds released as a result of an MRSDA career award must receive prior written approval of the program administrator.

Special Leave

Leave to another institution, including a foreign laboratory, may be permitted if directly related to the purpose of the award. Only local, institutional approval is required if such leave does not exceed three months. For longer periods, prior written approval of the awarding organization is required. To obtain prior approval, the award recipient must submit a letter to the institute describing the plan, countersigned by his or her department head and the appropriate local institutional official. A copy of a letter or other evidence from the institution where the leave is to be taken must be submitted to assure that satisfactory arrangements have been made. Support from the career award will continue during such leave.

Leave without award support may not exceed 12 months. Such leave requires the prior written approval of the awarding institute and will be granted only in unusual situations. Support from other sources is permissible during the period of leave. Such leave does not reduce the total number of months of program support for which an individual is eligible. Parental leave will be granted consistent with the policies of the NIH and the grantee institution.

Termination or Change of Institution

When a grantee institution plans to terminate an award, the awarding institute must be notified in writing at the earliest possible time so that appropriate instructions can be given for termination. If the individual is moving to another eligible institution, career award support may be continued provided:

A new career award application is submitted by the new institution, the period of support requested is no more than the time remaining within the existing award period, and the new application is submitted far enough in advance of the requested effective date to allow the necessary time for review.

The awarding institute may require a review by an initial review group and/or the appropriate national advisory council or board. Alternatively, review may be carried out by staff within the awarding institute, depending upon the circumstances.

The Director of the NIH may discontinue an award upon determination that the purpose or terms of the award are not being fulfilled. In the event an award is terminated, the Director of the NIH shall notify the grantee institution and career award recipient in writing of this determination, the reasons therefor, the effective date, and the right to appeal the decision.

A final progress report, invention statement, and Financial Status Report are required upon either termination of an award or relinquishment of an award in a change of institution situation.

Budget

Detailed budget for Initial Budget Period - do not complete form page 4 of the PHS 398 (rev. 4/98). It is not required nor will it be accepted at the time of application. In some cases, it may be requested prior to award.

Budget for Entire Proposed Period of Support - Do not complete the categorical budget table on form page 5 in the PHS 398 (rev. 4/98). Only the requested total direct costs for each year and total direct costs for the entire proposed period of support should be shown. Begin the budget justification in the space provided, using continuation pages as needed.

Budget Justification

- * List the name, role on project and percent effort for all project personnel (salaried or unsalaried) and provide a narrative.
- * Justification for each person based on his or her role on the project and proposed level of effort.
- * Identify all consultants by name and organizational affiliation and describe the services to be performed.
- * Provide a narrative justification for any major budget items, other than personnel, that are requested for the conduct of the project that would be considered unusual for the scope of research. No specific costs for items or categories should be shown.
- * Facilities and Administrative costs will be calculated at the time of the award at an eight percent rate or at the institution's actual rate, whichever is lower. Applicants will be asked to identify the cost exclusions prior to award.
- * If consortium/contractual costs are requested, provide the percentage of the subcontract total costs (direct and indirect) relative to the total direct costs of the overall project. The subcontract budget justification should be prepared following the instructions provided above.

Biographical Sketch

A biographical sketch is required for all key personnel, following the modified instructions below. Do not exceed the two-page limit for each person.

- * Complete the education block at the top of the form page.
- * List current position(s) and those previous positions directly relevant to the application.
- * List selected peer-reviewed publications directly relevant to the proposed project, with full citation.
- * Provide information on research projects completed and/or research grants participated in during the last five years that are relevant to the proposed project. Title, principal investigator, funding source, and role on project must be provided.

Other Support

Do not complete the Other Support page of the PHS 398. Instead include information on relevant grant support within the biosketch for each of the key personnel. Information on active support for key personnel will be requested prior to award. It is still necessary, however, to provide information about the research activity of the sponsor and co-sponsor on mentored career awards. Information about the level and nature of the sponsor(s) research support will continue to be used by review committees to judge the strength of the research environment available to the candidate during the award period.

Applicants are to provide information on the sponsor's and cosponsor's current and pending research support relevant to the candidate's research plan in a table within the section titled Statement by the Sponsor(s), Consultant(s), and Collaborator(s) in Section II, Part 2 of the application. Within this table, the following information on all related research projects must be provided: the funding source, the title of the project, the name of the principal investigator, the dates of the approved or proposed project, the annual direct costs, and a brief description of the major goals.

The application must address the following issues:

Candidate

- * Establish the candidate's commitment to a career in research ethics.
- * Establish the candidate's potential to develop into a successful independent investigator or (for more senior candidates) establish that the candidate has achieved a successful independent career in biomedical, behavioral, or public health research.
- * Summarize the candidate's immediate and long-term career objectives, explaining how the award will contribute to their attainment.

* Letters of recommendation. Three sealed letters of recommendation addressing the candidate's potential for a career in research ethics must be included as part of the application.

Career Development Plan

* Describe the career development plan, incorporating consideration of the candidate's goals and prior experience. It should describe a systematic plan to obtain the necessary background and research experience to launch a career in research ethics.

Research Plan

* The candidate and mentor together must describe the research plan as outlined in form PHS 398 including sections on the Specific Aims, Background and Significance, Progress Report/Preliminary Studies, Research Design, and Methods.

Mentor's Statement

* The application must include information on the mentor(s), including research qualifications and previous experience as a research supervisor. The application must also include information that describes the nature and extent of supervision that will occur during the proposed award period.

Environment and Institutional Commitment

* The sponsoring institution must document a strong, well-established research program related to social, ethical, and legal issues stemming from biomedical and behavioral research, including a high-quality research environment with staff capable of productive collaboration with the candidate. The sponsoring institution also must provide a statement of commitment to the candidate's development into a productive, independent investigator.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513), and in the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18, 1994, Volume 23, Number 11.

Investigators may obtain copies from these sources or from the program staff or contact person listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and which is available at the following URL address: <http://www.nih.gov/grants/guide/notice-files/not98-024.html>

Investigators may obtain copies from these sources or from program staff listed in INQUIRIES below who may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

Applications are to be submitted on form PHS 398 (rev. 4/98). Application kits are available at most institutional offices of sponsored research and may be obtained from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301/435-0714, email: GrantsInfo@nih.gov. Applications are also available on the World Wide Web at <http://www.nih.gov/grants/forms.htm>.

For purposes of identification and processing, the PA title and number must be typed in item 2 on the face page of the application and the "YES" box must be marked.

The completed, signed original and five legible, single-sided copies of the application and five copies of the appendices must be sent or delivered to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040, MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

Applications must be received by the application receipt date of March 6.

Only domestic institutions are eligible to apply for support under this program announcement. Potential applicants are encouraged to discuss their plans and objectives of their proposed courses with the NIH staff listed under INQUIRIES before submitting an application.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by the NIH Center for Scientific Review (CSR). Incomplete applications will be returned to the applicant without further consideration.

Applications received in response to this program announcement will be reviewed for scientific and technical merit by an initial review group in the CSR, in accordance with standard NIH peer review procedures. As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed and assigned a priority score and receive a second level of review by the National Advisory Allergy and Infectious Diseases Council.

Review Criteria

The following review criteria will be applied:

Candidate

* Is the candidate appropriately trained and suited to the proposed career development activities; i.e., well trained and productive in his or her current field and prepared for the proposed career development activities?

Career Development Plan

* Is the career development plan proposed one which will give the candidate sufficient grounding in principles, content, and methods of research ethics such that the candidate can establish an independent research career in the field?

Research Plan

All candidates for this award will have had previous research experience and in some cases will have been principal investigators in other scientific fields. A sound research plan that is consistent with the career development plan and the candidate's level of research development must be provided.

Significance: Does this project address an important problem? How well does the proposed research experience complement the proposed career development activities?

Approach: Are the methods adequately developed, well-integrated, and appropriate to the research plan and career development goals of the candidate? Does the candidate acknowledge potential problem areas and consider alternative tactics?

Mentor

* Is the mentor sufficiently qualified, experienced, and available to assist the candidate sufficiently in the proposed career development and research activities?

Institutional Environment and Commitment

* Is the institution's (or institutions' - if the trainee and mentor are located at different institutions) commitment sufficient to increase the probability of success? Is there appropriate collaboration among departments and units within the institution? Are there unique features in the institutional environment that can increase the chances of success? Are the resources adequate?

* Is the applicant institution willing to develop an appropriate mix of research, teaching, and administrative responsibilities for the candidate?

In addition to the above criteria, in accordance with NIH policy, all applications will also be reviewed with respect to the following criteria where they are applicable:

* The adequacy of plans to include both genders, minorities, and their subgroups as appropriate for the scientific goals of any research activities. Plans for the recruitment and retention of human participants will also be evaluated.

* The reasonableness of the proposed budget and duration in relation to the proposed activities.

* The adequacy of the proposed protection for humans, animals, or the environment to the extent they may be adversely affected by the activities proposed in the application.

AWARD CRITERIA

Funding decisions will be made based on the recommendations of the initial review group and the appropriate national advisory council and the availability of funds.

INQUIRIES

Written and telephone inquiries concerning this PA are encouraged, especially during the planning phase of the application.

Inquiries regarding programmatic issues may be directed to:

Milton J. Hernandez, Ph.D.
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
6003 Executive Boulevard, Room 3C21
Bethesda, MD 20892-7640
Telephone: (301) 496-3775
FAX: (301) 402-0369
Email: mh35c@nih.gov

Direct inquiries regarding fiscal matters to:

Barbara Huffman

Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
6003 Executive Boulevard, Room 3C25
Bethesda, MD 20892-7640
Telephone: (301) 496-3821
FAX: (301) 402-0369
Email: bh23q@nih.gov

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Nos. 93.855 and 93.856. The MRSDA awards are made under the authority of Title III, Section 301 of the Public Health Service (PHS) Act as amended. The Code of Federal Regulations, Title 42 Part 52, and Title 45 part 74, are applicable to this program. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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